HEALTH AWARENESS TESTING

REQUESTS MUST BE RECEIVED 14 DAYS PRIOR TO THE TESTING EVENT

NOTIFICATION OF CANCELLATIONS MUST BE RECEIVED WITHIN 48 HOURS

To perform Health Awareness testing in the District of Columbia you will need federal Clinical Laboratory Improvement Amendments (CLIA) certification. Health Awareness testing includes waived lipid testing, glucose, and hemoglobin A1C. Not all laboratory tests are considered waived and paying special attention to package inserts for reagents, test kits, test strips, and instrument manuals are required and must be maintained A copy of the CLIA permit must be posted at the location where testing is performed. An unannounced survey may be performed on the day of the screening.

If you are performing waived COVID-19 testing, you are required to complete a Communicable and Reportable Disease Testing application. A Communicable and Reportable Disease (infectious disease) letter will be forwarded by email to your facility until a permit is mailed. A copy of the letter must be posted at the location where testing is performed.

Before the test system may be used at a temporary or mobile laboratory test site, analyze two levels of quality control materials required by the manufacturer.

Submit a copy of documentation as written in the Standard Operating Procedure Manual (SOPM) to: michele.tallent@dc.gov

- Maintenance documentation
- Testing personnel training

Submit a copy of worksheets used for documentation of laboratory activities as part of the written SOPM to: michele.tallent@dc.gov

- Quality control worksheet including the lot number and expiration date
- Final report form that is given to the participant (include name, address and phone number of the laboratory)
- Consent form for participant to sign
- Occupational Safety and Health Administration (OSHA) safety regulations for occupational exposure to bloodborne pathogens

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E-MAIL HEALTH AWARENESS TESTING SITE REQUEST FORM TO: michele.tallent@dc.gov

DATE OF REQUEST: _____

FEDERAL CLIA NUMBER OF LABORATORY PERFORMING THE TESTING: _____

[ ] THIS IS AN INITIAL REQUEST. (IF THIS IS AN INITIAL REQUEST, SUBMIT A COPY OF THE DIRECTOR'S LICENSE WITH THIS FORM)

DATE AND TIME OF SCREENING EVENT: _____

COMPLETE ADDRESS OF SCREENING SITE:

_____

_____

TESTS TO BE PERFORMED:

_____

_____

NAME OF TESTING PERSON(S):

_____

EMAIL ADDRESS TO WHICH THE SITE APPROVAL CAN BE FORWARDED (UPON COMPLETION OF SUBMITTED DOCUMENTS):

_____

LABORATORY DIRECTOR SIGNATURE/DATE: _____

FORM COMPLETED BY SIGNATURE/DATE: _____

Office Use: Approved ☐ **Not Approved** ☐

3/2021

Code of the District of Columbia

§ 44–202. License requirements for clinical laboratories

§ 44–207. Inspections